UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,871	02/20/2004	Bonnie Hepburn	29635-714.201	7593

21971 7590 10/20/2008
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
POLANSKY, GREGG	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,871	HEPBURN ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 52-69* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,20-33 and 52-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' response, filed 6/27/2008, to the Office Action mailed 12/28/2007 is acknowledged. Applicants canceled Claims 34 and 35, amended Claims 1, 5, 10, 16, 17, 29-31, 33, 52, 53, 59-61, 63, 64, and 69, and presented arguments in response to the Office Action.

2. Applicants' Information Disclosure Statement, filed 9/30/2008, is acknowledged and has been reviewed to the extent each is a proper reference on a U.S. Patent.

3. Claims 1-33 and 52-69 are pending.

4. Claim 1-17, 20-33 and 52-59 are presently under consideration.

5. Applicants' arguments have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-17, 20-33, and 52-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to practice the invention. The claims are directed to the prevention or treatment of GERD symptoms comprising administering an acid labile proton pump inhibitor (a) and a buffering agent (b). The Specification does not reasonably provide enablement for the methods of prevention within the full scope of the claimed compounds. To be enabling, the Specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *PPG v. Guardian*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547, the court recited eight factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are: 1) the quantity of experimentation necessary 2) the amount of direction or guidance provided 3) the presence or absence of working examples 4) the nature of the invention 5) the state of the art 6) the relative skill of those in the art 7) the predictability of the art and 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The invention is drawn to treating or preventing gastroesophageal reflux disease (GERD) symptoms. The relative skill of those in the art is high, generally that of an M.D. or Ph.D. with expertise in the area of gastroenterology.

However, that factor is outweighed by the unpredictable nature of GERD. In cases involving unpredictable factors, such as the instant claims drawn to physiological activity, the scope of enablement varies inversely with the degree of unpredictability of the factors involved. One skilled in the chemical or biological arts cannot always reasonably predict how different chemical compounds might behave under varying circumstances. See *Ex parte Sudilovsky* 21 USPQ2d 1701.

The amount of direction or .guidance provided and the presence or absence of working examples

The instant Specification is drawn to a showing of the pharmacokinetics and pharmacodynamics of omeprazole/sodium bicarbonate compositions (pages 69-89). These showings are clearly not predictive for prevention of GERD symptoms. For example, a reduction of gastric acid (i.e., increase in gastric pH) is not necessarily

predictive of the prevention of heartburn. The skilled artisan would not reasonably expect that the claimed pharmaceutical combination composition could be used to prevent GERD symptoms.

There are no working examples drawn to a prevention modality in which the claimed pharmaceutical combination composition comprising both an acid labile proton pump inhibitor (a) and a buffering agent (b) is shown to be clinically effective for prevention of GERD symptoms.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to the efficacy of any other acid labile proton pump inhibitor, other than omeprazole, or any other buffering agent, other than sodium bicarbonate. The skilled artisan would expect the interaction of particular compounds in the prevention of GERD symptoms to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for the combination of agents. The instant specification sets forth no such understanding. No direction is provided to distinguish therapy among the various compounds that are encompassed in parts (a) and (b) of Claim 1. No correlation is presented for a decrease in gastric acid (i.e., increase in gastric pH) and prevention of GERD symptoms. Absent reasonable *a priori* expectations of success for using a particular pair of an acid labile proton pump inhibitor and a buffering agent, one skilled in the art would have to test extensively many combinations to discover which combination in particular exhibits an effect in treating or preventing GERD symptoms. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically

tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The Specification provides inadequate guidance to do otherwise.

Due to the known unpredictability of the art, and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that GERD symptoms could be prevented following the administration of any combination of an acid labile proton pump inhibitor with any buffering agent. Accordingly, the instant claims do not comply with the enablement requirements of 35 U.S.C. 112, first paragraph, since to practice the claimed invention would require a person of ordinary skill in the art to engage in undue experimentation with no assurance of success.

Applicants argue the"[t]erm "prevent" or "prevention" as relates to a gastrointestinal disorder or disease, has been defined in the specification". Further, Applicants urge "where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim".

It is the Examiner's position that the claims are not enabled for prevention for reasons of record (*supra*), even when the claims are examined using Applicants' definition of the term "prevent" or "prevention". Most importantly, no clinical data is presented which demonstrates a prevention of GERD symptoms (e.g., heartburn) by the administration of the instant compositions. Absent such clinical data, Applicants have not demonstrated that increasing gastric pH prevents GERD symptoms.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-17, 20-33 and 52-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Patent No. 6,489,346 B1), in view of Hatlebakk et al. (Alimentary Pharmacology and Therapeutics, 2000, Vol. 14, pages 1267-1272).

Phillips teaches a pharmaceutical composition comprising a non-enteric coated proton pump inhibitor, in an amount of approximately 5 mg to approximately 300 mg, and a least one buffering agent, in an amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor. See Abstract. Phillips teaches the composition can be formulated as a powder, tablet, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets and graduals and liquids. The buffering agent is utilized to protect the proton pump inhibitor against gastric acid degradation. See column 11 lines 13-32. Phillips teaches

omeprazole/sodium bicarbonate formulations wherein omeprazole is present in the formulation in the amount of 5 mg, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg and 100 mg. See column 39, claim 1 and column 41, claims 36-41. The reference further teaches the formulation buffering agent (i.e., sodium bicarbonate) is present in the amount of 400 mg to 4000 mg. See column 42, claim 59. The proton pump inhibitor can be an enantiomer, isomer, derivative, free base or salt of the parent compound. See column 42, claim 57. Phillips teaches the proton pump inhibitor can be micronized. See column 41, claim 49. The composition taught further comprises excipients, including flavoring agents, diluents, disintegrants, lubricants, preservatives and lubricants. See column 44, claim 116. Furthermore, Phillips teaches methods of treating gastrointestinal conditions, including GERD, by administration of the proton pump inhibitor/buffer formulations described above (including omeprazole/sodium bicarbonate). See column 12, lines 39-49.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). Phillips teaches proton pump inhibitor/buffering agent compositions that are identical to those recited by the instant invention (*supra*). Therefore, the pharmacokinetic and pharmacodynamic characteristics of the compositions taught by Phillips would be the

same as those recited by the instant claims. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Phillips does not disclose *per se* the administration of the proton pump inhibitor compositions within about 60 minutes prior to a meal, as required by the instant claims.

Hatlebakk et al. teach the administration of the proton pump inhibitors, omeprazole and lansoprazole, 15 minutes prior to a meal, to provide better acid suppression. See page 1267, "SUMMARY".

One skilled in the art of pharmaceutical formulation is provided with guidelines from Phillips, sufficient to prepare formulations comprising a proton pump inhibitor, such as omeprazole, in combination with a buffer, such as sodium bicarbonate, to treat patients suffering from GERD. The reference teaches or suggests each limitation of the present claims. It is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See In re Aller, 220 F.2d 454, 456, 105 USPQ233,235 (CCPA 1955) and MPEP 2144.05(11). The determination of the optimum dosages, particle sizes, gastric fluid pH ranges,

serum concentrations over time and drug release rates to employ or to seek with the presently claimed agents, would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts, particle sizes, serum concentrations over time and drug release rates are not seen to be inconsistent with those that would have been determined by the skilled artisan.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Phillips with those of Hatlebakk et al. The teaching of Hatlebakk et al. that administration of proton pump inhibitors 15 minutes prior to a meal improves acid suppression would have motivated one to do so; to provide an improved treatment of GERD symptoms.

11. Claims 1-17, 20-33 and 52-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Patent Application Pub. No. 2003/0191159 A1), in view of Hatlebakk et al. (*Ibid.*).

Phillips teaches methods and compositions for treating gastric acid disorders, including *inter alia* GERD and heartburn, employing pharmaceutical compositions

comprising an acid labile proton pump inhibitor and a buffering agent. See Abstract, and page 11, paragraph 100, and page 54, claim 122. Phillips teaches the composition can be formulated as a powder, tablet, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets and graduals and liquids. The buffering agent is utilized to protect the proton pump inhibitor against gastric acid degradation. See page 5, paragraph 37 and page 52, claim 37. Phillips teaches the proton pump inhibitors are present in the composition in amounts from 5 mg to 1000 mg and unit doses of 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 40 mg, 50 mg, 60 mg, 75 mg, 80 mg, or 100 mg. See page 10, paragraphs 84 and 85. The reference teaches the buffering agent present in the composition in an amount of 0.1 mEq to 2.5 mEq per mg of proton pump inhibiting agent. The reference further teaches the formulation buffering agent (i.e., sodium bicarbonate) is present in the amount of 250 mg to 4000 mg. See page 52, claim 26. The proton pump inhibitor can be in the form of a salt, ester, amide, enantiomer, isomer, tautomer, prodrug, derivative. See page 7, paragraph 65. Phillips teaches the proton pump inhibitor can be micronized. See page 13, paragraph 131. The composition further comprises excipients, including flavoring agents, diluents, disintegrants, lubricants, preservatives and lubricants. See page 53, claim 70. The reference teaches the proton pump inhibitor can be enteric coated or uncoated. See page 5, paragraphs 37 and 38, and page 52, claim 45. The Phillips reference teaches that the composition buffering agent is present in an amount sufficient to increase gastric fluid pH of the stomach to a pH that inhibits acid degradation of the proton pump inhibitor agent in the gastric fluid, so as to allow

absorption of the proton pump inhibiting agent and to provide a therapeutically effective serum concentration of the proton pump inhibitor of at least 150 ng/ml within 15 minutes after ingestion of the composition. See page 52, claim 37. Phillips teaches an omeprazole T_{max} of less than 1.5 hours with a C_{max} ranging from 763 ng/ml to 1460 ng/ml for an omeprazole/sodium bicarbonate composition. See page 30, paragraph 325 and Table 9. Phillips further teaches a plethora of additional pharmacokinetic and pharmacodynamic information on proton pump inhibitor/buffering agent compositions. One of skill in the art would recognize that the pharmacokinetic and pharmacodynamic characteristics of a composition are complex and depend upon *inter alia* the age, body weight, general health, and sex of the patient, the rate of excretion, the drug combination and formulation, and the route of administration.

As discussed *supra*, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). Phillips teaches proton pump inhibitor/buffering agent compositions and methods that are identical to those recited by the instant invention. Therefore, the pharmacokinetic and pharmacodynamic characteristics of the compositions taught by Phillips would be the same as those recited by the instant claims.

Phillips does not disclose *per se* the administration of the proton pump inhibitor compositions within about 60 minutes prior to a meal, as required by the instant claims.

Hatlebakk et al. teach the administration of the proton pump inhibitors, omeprazole and lansoprazole, 15 minutes prior to a meal, to provide better acid suppression (*supra*).

One skilled in the art of pharmaceutical formulation is provided with guidelines from Phillips, sufficient to prepare formulations comprising a proton pump inhibitor, such as omeprazole, in combination with a buffer, such as sodium bicarbonate, to treat patients suffering from GERD. The reference teaches or suggests each limitation of the present claims. It is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See In re Aller, 220 F.2d 454, 456, 105 USPQ233,235 (CCPA 1955) and MPEP 2144.05(11). The determination of the optimum dosages, particle sizes, gastric fluid pH ranges, serum concentrations over time and drug release rates to employ or to seek with the presently claimed agents, would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed

specific dosage amounts, particle sizes, serum concentrations over time and drug release rates are not seen to be inconsistent with those that would have been determined by the skilled artisan.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Phillips with those of Hatlebakk et al. The teaching of Hatlebakk et al. that administration of proton pump inhibitors 15 minutes prior to a meal improves acid suppression would have motivated one to do so; to provide an improved treatment of GERD symptoms.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Applicants argue, with regard to both references to Phillips, that administration of the compositions prior to a meal is not taught or suggested. The reference to Hatlebakk et al. has been provided to overcome this deficiency.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-17, 20-33 and 52-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-11, 13-39, 41, 44, 45 and 47-63 of copending Application No. 10/938766; Claims 44-85 of copending Application No. 10/893092; Claims 1-35 of copending Application No. 11/107349; Claims 1-15, 17, 18, 20-25, 54, 56-86 of copending Application No. 10/893203; Claims 48-58 of copending Application No. 11/138763; and Claims 1-55 of copending Application No. 10/982369 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending applications are drawn to compositions and methods of treating GERD or gastric acid-related disorders comprising administering at least one substituted bicyclic aryl-

imidazole acid labile proton pump inhibitor and at least one buffering agent, and pharmaceutical compositions thereof. The claims in the '349 application additionally require at least one 5-HT inhibitor. The claims in the '092 application additionally require at least one flavoring agent. The claims in the '763 application additionally require at least one disintegrant. The claims in the '369 application require at least one antihistamine sleep aid. However, the addition of any number of active (or inactive) components is permitted, in view of the open language of the present claims.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Applicants choose to hold the provisional (obviousness-type) double patenting rejections in abeyance. Accordingly, the rejections of record of Claims 1-17, 20-33 and 52-59 are maintained.

Conclusion

15. Claims 1-17, 20-33 and 52-59 are rejected.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614